DoD Smallpox Vaccination Program
Safety Summary, May 14, 2004

Background:

On December 13, 2002, the President directed smallpox vaccinations for selected military personnel, government workers, and contracted workers. DoD vaccinations began immediately for emergency response personnel and hospital staff members. Comprehensive training programs in vaccination technique, infection-control safeguards, screening and education methods, adverse event monitoring, and product storage and handling, aggressively launched in October 2002, made immediate vaccinations possible. In early January 2003, DoD began smallpox vaccinations of selected US military forces, and emergency-essential civilians and contractors deployed or deploying in support of U.S. Central Command missions.

Program Status:
DoD operational forces and healthcare workers vaccinated against smallpox: over 625,000. Detail about the DoD program appeared in the June 25 issue of the Journal of the American Medical Association (JAMA).The abstract of that article appears after the following summation of the program's current status:

In the 17 months between 13 Dec 02 and 10 May 04, the DoD administered 623,244 smallpox vaccinations. Most adverse events occurred at rates below historical rates. One case of encephalitis and 75 cases of acute myo-pericarditis developed after vaccination. Among 27,700 smallpox-vaccinated health-care workers, there were no cases of transmission of vaccinia from worker to patient. Thirty-five cases of contact transfer of vaccinia virus have occurred, principally to spouses and adult intimate contacts. No cases of eczema vaccinatum or progressive vaccinia occurred, and the total number of treatments with vaccinia immune globulin (VIG) remains at three. Thirty-six cases of generalized vaccinia were treated, primarily as outpatients. Six deaths due to disease after vaccination have been reviewed: one following an acute lupus-like illness may have been caused by vaccination, based on review by two independent panels of civilian physicians. Additional information on this case appears at http://www.smallpox.mil/event/www.vaccines.mil/panelreport.asp. The other five deaths involved one each of the following diagnoses: myocardial infarction, atherosclerotic coronary vascular disease,

pulmonary embolism, heat injury, and benzodiazepine overdose. These deaths were judged unrelated to vaccination, based on individual factors such as preexisting disease, incidence among unvaccinated people, and lack of physical evidence to implicate a vaccine.

NOTE: All appropriate program information is provided regularly to federal health authorities, including all safety-surveillance data.

The June 25, 2003, issue of the Journal of the American Medical Association (JAMA) summarizes the DoD experience with smallpox vaccination to date. Below appears the abstract of this article:

US Military Smallpox Vaccination Program Experience John D. Grabenstein, RPh, PhD
William Winkenwerder, Jr., MD, MBA

Context. The United States recently implemented smallpox vaccination of selected military personnel in a national program of preparedness against use of smallpox as a biological weapon. The return of smallpox vaccinations raises important questions regarding implementation and safety.
Objective. To describe the US military smallpox vaccination program.
Design. Descriptive study of the vaccination program from its inception on December 13, 2002, through May 28, 2003.
Setting. US Department of Defense (DoD) fixed and field medical treatment facilities on multiple continents and ships at sea.
Subjects. US service members and DoD civilian workers eligible for smallpox vaccination.
Main Outcome Measures. Numbers of vaccinations and rates of vaccination exemptions, symptoms, and adverse events. Data was collected via reports to headquarters and rigorous surveillance for sentinel events.
Results. In 5.5 months, the DoD administered 450,293 smallpox vaccinations (70.5% primary vaccinees and 29.5% revaccinees). In 2 settings, 0.5% and 3.0% of vaccine recipients needed short-term sick leave. Most adverse events occurred at rates below historical rates. One case of encephalitis and 37 cases of acute myopericarditis developed after vaccination; all cases recovered. Among 19,461 worker-months of clinical contact, there were no cases of transmission of vaccinia from worker to patient, no cases of eczema vaccinatum or progressive vaccinia, and no attributed deaths.
Conclusions. Mass smallpox vaccinations can be conducted safely with very low rates of serious adverse events. Program implementation emphasized human factors: careful staff training,

contraindication screening, recipient education, and attention to bandaging. Our experience suggests broad smallpox vaccination programs may be implemented with fewer serious adverse events than previously believed. JAMA. 2003;289:3278-3282 www.jama.com

Full article at: http://jama.ama-assn.org/cgi/reprint/289/24/3278.pdf

For more discussion of the first 18 myo-pericarditis cases, see: http://jama.ama-assn.org/cgi/reprint/289/24/3283.pdf

For the accompanying editorial, see: http://jama.ama-assn.org/cgi/reprint/289/24/3306.pdf

Perspective:

"Within DoD, we know a lot now about smallpox vaccine. We now have current, good experience with using it. The remarkable news about this program is that our adverse events do not reflect what history told us to expect. With proper care and attention, smallpox vaccine can be administered to large numbers of people safely. Those large numbers of vaccinated citizens discourage an enemy from using smallpox as a weapon."

- William Winkenwerder, Jr., MD, Assistant Secretary of Defense for Health Affairs